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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,548

09/15/2006

Andrea Heger

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,548	Applicant(s) HEGER ET AL.	
	Examiner Sandra Saucier	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1–11 are pending. Claims 1–10 are considered on the merits. Claim 11 is withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claim 11 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected . Election was made without traverse in Paper No. 3/26/09.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must

fully comply with 37 CFR 3.73(b).

Claims 1–10 are provisionally rejected on the ground of nonstatutory obviousness–type double patenting as being unpatentable over claims 11–28 of copending Application No. 12/222,457. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope.

This is a provisional obviousness–type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1–10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims should have a preamble and a transition phrase “comprising” etc. If it is a product by process claim, it should have process steps, i.e. “mixing”, by definition.

The definition of Caucasian according to the Random House Dictionary [U] is a person with fair to dark skin, straight to tightly curled hair and light to very dark eyes inhabiting Europe, parts of North Africa, Western Asia and India. Caucasian in its alternate definition relates to the inhabitants around the Caucasus mountains, i.e. Georgians, Abkhazians, Avars, etc. who speak languages that belong to the Caucasian language family. Thus, the definition of Caucasian is a varying one, sometimes it means “white people” which does not include the “yellow races”, into which Asians are sometimes classified. It is not a modern scientific term, but is more of a political term with varying definitions according to political desires. Races delineations promoted by Carleton Coon in 1962 used such terms as Caucasoid, Mongoloid, Australoid, Negroid and thus places Asians into a different classification from Caucasoid,

which is in conflict with the previous dictionary definition of Caucasian.

The term “non-Caucasian population” is indefinite because it is a definition which requires a person to be either Caucasian or not. There are no gradations of categorization. For example, is a person born of a native Kenyan father and an Irish mother a non-Caucasian or a Caucasian, since that person has inherited half European and half African DNA from parents with these geographical origins. Which half will be the dominating classification, surely this is arbitrary. Also, the “Hispanic” classification includes people whose geographical origins are European as well as African. Are all Hispanics then non-Caucasian, even though they may have, for example, Incan, Spanish or even Jewish ethnic or geographical origins?

Caucasian and its inverse, non-Caucasian are terms which are not scientifically accurate according to present-day knowledge and therefore have no precise and agreed upon definitions and which have no set metes and bounds and are therefore, indefinite.

If applicants wish to identify a plasma with certain characteristics, they should use scientifically unambiguous terminology, such as concentrations of markers.

Claim 4 uses the terms “such as” and “like”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for

Art Unit: 1651

example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim 5 uses the term “such as”. If applicants wish to limit the claim to caprylate, they should do so.

Use of the past tense “was inactivated”, “was performed” is discouraged. Steps in a method have active verbs, inactivating, performing etc..

Claim 10 provides for the use of the plasma of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Please cancel claim 10. Claims introduced to methods of use or making at this stage in the prosecution will be withdrawn in the next examiner's action.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–3, 6–10 are rejected under 35 U.S.C. 103(a) as being

Art Unit: 1651

unpatentable over WO 99/07390 [IDS] in view of Aubert *et al.* [V].

The claims are directed to a plasma composition comprising:

5–6 parts plasma from type A donors,

4–5 parts plasma from type B donors,

0–1 parts plasma from type AB donors

0 parts plasma from type O donors.

Therefore, simple calculation determines that the ranges in the claim allow (rounded off),

45–60% of the plasma to be from type A donors,

36–50% of the plasma to be from type B donors,

0–10% of the plasma to be from type AB donors,

with no plasma from type O donors.

Dependent claims require the titer for anti–A and anti–B IgM to be lower than 16 and for anti–A and anti–B IgG to be lower than 64.

The references are relied upon as explained below.

WO 99/07390 teach a plasma composition comprising:

6–10 parts plasma from type A donors,

1–3 parts plasma from type B donors,

0–1.5 parts plasma from type AB donors,

0 parts plasma from type O donors page 2.

Therefore, by calculation,

57 to 91% plasma from type A donors,

8 to 33% plasma from type B donors,

0 to 17% plasma from type AB donors,

0 parts plasma from type O donors.

The plasma has a titer of lower than 16 for anti–A and anti–B IgM, and

lower than 64 for anti-A and anti-B IgG (page 4).

Detergent/solvent virus inactivation processes are also taught as well as frozen, lyophilized, fresh liquid forms (page 3).

Aubert *et al.* teach the principle of neutralization of plasma or serum by making the agglutinin and iso-agglutinin contents of the plasma neutralize each other by pooling suitable amounts of plasma or whole blood from different blood groups and measuring the resultant titer (page 102). This is the theoretical construct of the instant invention.

With regard to the differences in concentrations between the instant claims and the disclosure of the prior art, see MPEP 2144.05 I. and II.

Generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation, *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

One of skill in the art is fully capable of mixing plasmas from different blood group donors in a fashion so as to reduce the anti-A, anti-B IgG and IgA titers to any level desired, particularly since there are standard tests for these antibodies and Aubert *et al.* has taught the basic principles involved. The crux of the invention is to produce a plasma with negligible iso-agglutinin titers for transfusion purposes. Whether the plasma is obtained from populations which are termed "non-Caucasian" or not is of little patentable weight particularly since that term is ambiguous. It is the titer of the antibodies in the plasma which is critical not the skin color of the human from which it is derived.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/07390 [IDS], Aubert *et al.* [V] as applied to claims 1-3, 6-10 above,

and further in view of US 2003/0133829 [A].

The claims are further directed to the use of various chemicals to inactivate virus in plasma.

US 2003/0133829 in the Background of the Invention [0003-0012], describes known processes which employ solvent and detergents such as Triton and fatty acids such as caprylic acid to inactivate virus in biological products such as plasma.

The employment of any known process to inactivate virus in the process of producing a universal plasma taught by WO 99/07390 would have been obvious when taken with US 2003/0133829 which describes such viral inactivation processes, particularly because WO 99/07390 invites the use of any known viral inactivation process on page 3.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651